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GLAXOSMITHKLINE

17 UNITED STATES DISTRICT COURT
18 NORTHERN DISTRICT OF CALIFORNIA
19 OAKLAND DIVISION

20 SMITHKLINE BEECHAM CORPORATION,
d/b/a GLAXOSMITHKLINE,

21 Plaintiff,

22 vs.

23 ABBOTT LABORATORIES,

24 Defendant.

Case No. C07-5702 (CW)

SECOND AMENDED COMPLAINT

DEMAND FOR JURY TRIAL

INTRODUCTION

Plaintiff SmithKline Beecham Corporation, d/b/a GlaxoSmithKline (“GSK”), by and through its undersigned attorneys, alleges as follows:

1. This case is about the attempt of Abbott Laboratories (“Abbott”) to dominate the markets into which one of the most promising new HIV/AIDS therapies – protease inhibitors (“PIs”) – are sold. Abbott schemed to remove from those markets one of the critical components of PI therapy – a boosting agent called Norvir® (branded ritonavir) – when, overnight and in a radical departure from its long-standing pattern of taking incremental price increases, it raised the price of that component by 400 percent. Abbott’s action forced those patients using most of the FDA-approved PI therapies either to pay the exorbitant new price or to use Abbott’s PI, known as Kaletra® (branded lopinavir/ritonavir). Kaletra is a combination drug whose price Abbott did not increase despite the fact that it also contains the same boosting agent as Norvir. Abbott’s scheme protected Kaletra against new competitors that threatened its market dominance, in violation of the law.

2. But Abbott’s action did more than violate the law – it targeted one competitor, GSK, in violation of principles of fair business conduct and a license agreement that Abbott itself had demanded of GSK. A year before its price hike, Abbott had extracted substantial sums of money from GSK as part of an agreement that allowed GSK to market and promote its yet-to-be-launched PI, Lexiva® (branded fosamprenavir), specifically for boosting with Norvir. Then, two weeks after GSK launched Lexiva, Abbott entirely disregarded its paid-for contractual obligations and took its extraordinary Norvir pricing action. That action was designed to render Norvir essentially inaccessible to a wide array of patients for use with Lexiva and other competitive products. Abbott’s misconduct is particularly egregious because Abbott explicitly considered the negative impacts of its price hike – the costs to AIDS/HIV patients, the harmful impact on its competitors, the losses to its contract partners, the likelihood of potential government investigation, and the harm to its own reputation – and decided it was worthwhile to go ahead with the price hike because the profits it expected to generate from sales redirected to Kaletra were so

1 enormous. Internal Abbott documents, including, for example, those recently made public through
 2 the Wall Street Journal, attached as Exhibits A & B, reveal:

- 3 • Abbott executives understood the illegal nature of their scheme and sought to
 4 “minimize any federal investigations regarding price increases in the US.”
- 5 • They also understood that adverse consequences would result if their scheme
 6 was discovered, stating that it would “[t]arnish” their CEO’s reputation,
 7 “[p]osition [Abbott] as a big, bad, greedy pharmaceutical company,” and
 8 “[r]einforce[] perception[s] that Abbott is not committed to HIV.”
- 9 • To conceal the scheme, Abbott executives crafted excuses, for example, that
 10 “[i]t is no longer feasible for Abbott to provide a production line of Norvir
 11 capsules at the current price.” Yet, these same executives recognized that these
 12 justifications would be exposed as false if Abbott were “forced to open books.”

13 3. Abbott succeeded in its design, harming competition in the markets into which PIs
 14 are sold, harming GSK and Abbott’s other competitors in those markets and harming the
 15 HIV/AIDS community it was committed to serving. Despite the advent of new competition in
 16 2003, Abbott’s 2006 Annual Report still proclaims that “Kaletra remains the world’s leading
 17 protease inhibitor for HIV treatment.” In July of 2007, Abbott reported a 27 percent increase in
 18 pharmaceutical sales, “driven by strong double-digit growth” in Kaletra and three other drugs. In
 19 contrast, GSK’s Lexiva sales have fallen short of pre-release forecasts prepared for and by both
 20 GSK and Abbott. Abbott’s illegal conduct caused GSK to lose sales, profits and market share for
 21 Lexiva. In addition, Abbott’s illegitimate and unprecedented price increase deprived GSK of the
 22 benefit of the bargain GSK and Abbott struck when GSK paid Abbott substantial sums of money
 23 for a license allowing GSK to promote its PIs for boosting with Norvir. Abbott’s misconduct
 24 interfered with, and continues to interfere with, GSK’s ability to serve the HIV/AIDS community
 25 and to provide the treatments that HIV-positive patients need.

26 4. It is this community that Abbott’s misconduct hit hardest. As reported in the Wall
 27 Street Journal, one AIDS patient saw his insurance copayments jump from \$400 per month to
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1 \$1,000 per month because of the supracompetitive prices Abbott foisted on the market. Abbott's
 2 price increase has the effect of limiting the types of PIs available to patients – thus interfering with
 3 their ability to effectively treat the disease.

4 **PARTIES**

5 5. GSK is a Pennsylvania corporation with its headquarters in Research Triangle Park
 6 (Durham), North Carolina and Philadelphia, Pennsylvania. Its North Carolina locations are the
 7 base for the company's research and development facilities and commercial operations in the
 8 HIV/AIDS area, and they also house various sales and marketing, administrative, and corporate
 9 functions. GSK has been harmed in North Carolina by Abbott's misconduct.

10 6. Abbott is an Illinois corporation with its principal place of business in Abbott Park,
 11 Illinois. Abbott is engaged in the development, manufacture, and sale of health care products and
 12 services. Abbott has operations in six states. Of those, it has the most facilities in California (four),
 13 including in Alameda, Santa Clara, and Redwood City. Abbott sells its products, including Norvir
 14 and Kaletra, throughout the state of California and the United States.

15 **JURISDICTION, VENUE AND INTRADISTRICT ASSIGNMENT**

16 7. Abbott is subject to the jurisdiction of this Court by virtue of its business dealings,
 17 including sales and distribution of Kaletra and Norvir, in this District, and by having caused
 18 injuries within this District through its acts and omissions. GSK's damages are well in excess of
 19 the jurisdictional minimum in diversity actions.

20 8. Count one arises under state common law. Count two arises under the North
 21 Carolina Unfair Trade Practices Act, N.C. Gen. Stat. § 75-1.1.

22 9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. This Court
 23 has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

24 10. Abbott has business locations in this District, has transacted and continues to
 25 transact business in this District, has committed and continues to commit illegal acts in this
 26 District, and has harmed and continues to harm GSK in this District. Venue is therefore proper in
 27 this District under 28 U.S.C. § 1391(b) and (c).

11. Intradistrict assignment is proper in the San Francisco/Oakland Division, pursuant to L.R. 3-2(c) & (d), because a substantial part of the events which give rise to the claim occurred in Alameda, Contra Costa, Del Norte, Humboldt, Lake, Marin, Mendocino, Napa, San Francisco, San Mateo and Sonoma counties.

FACTUAL BACKGROUND

12. HIV/AIDS is one of the worst pandemics in human history. It already has claimed over 500,000 lives in the United States and 25 million worldwide. The quality of life of the 40 million people presently living with HIV/AIDS today depends on the effectiveness and availability of HIV treatments. Today, HIV is suppressed using highly active antiretroviral therapy (“HAART”). HAART treatment is effective because it combines three or four different drugs, attacking the HIV virus at different points in its lifecycle.

13. Protease inhibitors (“PIs”) attack the HIV protease enzyme necessary in one of the final stages of the HIV virus’s replication process. PIs are considered one of the most potent weapons in the HAART arsenal. GSK, Abbott, and Bristol Myers Squibb (“BMS”), among others, design, develop, and distribute PIs. Although PIs present an effective treatment, they have several impediments, including pill burden, dietary requirements and severe side effects. Each PI presents different degrees of impediment and efficacy. In addition, patients develop resistance to certain PIs as the disease progresses – a significant challenge to the treatment of HIV/AIDS. Thus, it is critical that patients have a wide variety of PIs available.

14. With significant funding assistance from the National Institutes of Health, Abbott developed ritonavir, brand named Norvir, which it launched in 1996, for use as a stand-alone PI. Abbott received funding assistance from the National Institutes of Health to research and develop Norvir, and GSK is informed and believes that Abbott spent significantly less in developing Norvir than typical for other major pharmaceutical drugs.

15. While Norvir proved to be a very difficult medicine to tolerate when used as a standalone PI, Abbott recognized even before its release that in smaller, less toxic doses Norvir could “boost” the effectiveness of a PI paired with it. This boosting effect reduces the dosage

1 amounts of the paired PI and thus the high pill burden on patients and, perhaps most important,
2 slows the development of resistance to any given PI treatment.

3 16. Shortly after Norvir's release doctors began to co-prescribe and co-administer
4 Norvir as a booster with other PIs. GSK and other Abbott competitors relied on the reasonable
5 availability of Norvir as a boosting agent when developing and designing their own PIs.

6 17. Abbott never sought to use its intellectual property to prevent others from selling
7 PIs for co-administration with Norvir. Instead, from early on, Abbott chose to encourage its
8 competitors to promote their PIs for boosting with Norvir and to profit from Norvir's boosting use
9 both by selling it at a profit and by licensing competitors the right to market PIs to be
10 coadministered with Norvir.

11 18. Thus, the competitive market for PIs boosted with Norvir continued uninterrupted;
12 based on Abbott's course of conduct, Norvir became the de facto standard. Since at least 2000,
13 Norvir has been regularly co-prescribed and co-administered with various PIs, including those
14 designed and developed by Abbott's competitors. Today, Norvir is sold almost exclusively as a
15 booster. Physicians recognize that Norvir is the only effective boosting compound available and is
16 an essential component of almost every PI-based treatment for HIV/AIDS.

17 19. In 2000, Abbott received government approval to market its own PI (called
18 lopinavir) boosted with the active ingredient in Norvir (called ritonavir), which it marketed as
19 Kaletra. Unlike its rivals, Abbott combined its PI (lopinavir) and Norvir (ritonavir) in a single pill.
20 Kaletra became and remains the only product on the market to combine a boosting dose of Norvir
21 with a PI in one pill. Kaletra quickly gained a very significant share of the market.

22 20. In 2001, Abbott approached GSK to demand that it secure a license to allow GSK
23 to promote its existing PIs, as well as PIs it had under development, with Norvir. GSK acquiesced
24 to this demand, procuring a license from Abbott in December 2002.

25 21. Under the agreement, Abbott gave GSK the right to promote the use and
26 administration of its PIs with Norvir. Abbott knew that GSK's plan was to use the Norvir license
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1 in order to promote GSK's PIs in boosted form. GSK paid substantial sums of money in
2 consideration for this license.

3 22. Abbott is the sole manufacturer of Norvir; thus, despite the license, GSK must rely
4 on Abbott to make and sell it. Upon entering into the agreement, Abbott was bound to act in good
5 faith to ensure that Norvir remained on the market for co-administration with GSK PIs, as it had
6 done in its previous course of dealings. Without the continued reasonable availability of Norvir,
7 the agreement would be illusory – GSK would have paid Abbott for nothing.

8 23. Other pharmaceutical companies, including BMS, took similar licenses allowing
9 the promotion of their PIs with Norvir during the same timeframe. By mid-2003 Abbott had
10 licensed nearly all manufacturers of protease inhibitors to promote their PIs for co-prescription
11 and coadministration with Norvir.

12 24. Abbott's strategy for exploiting Norvir was highly profitable for Abbott. In
13 addition to its licenses, it priced Norvir well above Abbott's per pill cost. Abbott then took
14 periodic price increases on Norvir that were tied to increases in the Consumer Price Index. Thus,
15 for seven years after its introduction, Abbott elected not to make any major adjustment to Norvir's
16 price taking price increases of not more than four percent per year. Abbott limited itself to small
17 adjustments in the price of Norvir despite knowing that its revenues per prescription were
18 continually decreasing as Norvir's predominant use steadily shifted to boosting other PIs. Through
19 Abbott's profitable licensing and pricing strategy, Abbott allowed and, indeed, encouraged others
20 to compete in the boosted PI marketplace.

21 25. Abbott changed this long-standing course of conduct in response to its realization
22 that its dominant boosted PI, Kaletra, would face strong competition from two new PIs, GSK's
23 Lexiva and BMS's Reyataz. Abbott engaged in a 15-month deliberative process that began in
24 September 2002 to evaluate and perfect a plan to protect Kaletra's market dominance. Faced with
25 the prospect of new competitors, Abbott's executives forsook legal approaches to defending
26 against a loss of market share. Its executives formulated an illegitimate scheme using Abbott's
27 control of Norvir as leverage to maintain or increase Kaletra's dominant market position. Abbott
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1 executives were well aware that Abbott had facilitated the use of Norvir as a booster and caused
2 its competitors to rely on the availability of Norvir – through Abbott’s past course of conduct and
3 formally through licensing its competitors to promote their PIs with Norvir. Abbott executives
4 realized that if Abbott could make Norvir unavailable or less desirable when paired with its
5 competitors’ PIs – by actually pulling it from the market or by manipulating its price – then its
6 competitors’ products, which by that time almost always relied on Norvir for boosting, would
7 never become a significant competitive threat to Kaletra’s market dominance.

8 26. Abbott also had an economic incentive unique to the pharmaceutical industry to use
9 its power over Norvir boosting to preserve Kaletra’s dominance of the boosted PI market. Pricing
10 rules for important government programs restricted the amount of money Abbott could obtain,
11 from sales of drugs that reached patients covered by those programs, by taking price increases
12 greater than the CPI-U. By contrast, if Abbott could maintain Kaletra’s market dominance, it
13 could circumvent these pricing rules and exploit its power over boosters because Abbott had
14 priced Kaletra at a price that reflected the market power Abbott achieved as a result of the
15 boosting capabilities of Norvir. Thus, by making Norvir less attractive when used as a booster
16 with non-Abbott PIs and thereby protecting Kaletra’s market share, Abbott was able to extract
17 additional and excessive revenue from payers that it could not otherwise extract.

18 27. Internal Abbott emails and other documents, some of which were released by the
19 Wall Street Journal, attached as Exhibits A and B, lay out exactly this scheme. One Abbott
20 executive explained Abbott’s concern: Abbott could not “continue to trade a prescription of
21 Kaletra for a prescription of Norvir at 100mg.” Rather than relying on any competitive advantage
22 in the medicinal characteristics of Kaletra, or even lowering Kaletra’s price so that it was more
23 attractive to patients, this executive outlined alternative schemes that had been discussed among
24 Abbott management and warned other senior Abbott employees not to be “stunned by the outcome
25 of the thought process.”

26 28. But Abbott’s documents and emails are stunning. In September 2002, during the
27 final months of its negotiations with GSK over the Norvir license, Abbott began to consider
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1 whether to remove Norvir from the United States market by “[g]iv[ing] the remaining supplies [of
 2 Norvir] to Africa and shut[ting] down the RTV [ritonavir] manufacturing line.” Abbott dubbed
 3 this option the “supply constraint program.” An email from one Abbott employee candidly reveals
 4 that the true purpose of this “[r]eallocation of Abbott product” is “to make physicians and patients
 5 switch to Kaletra....”

6 29. In 2003, as the threat from Lexiva and Reyataz persisted, Abbott evaluated what it
 7 termed the “Withdrawal Option” along with various pricing options. By late summer, Abbott had
 8 boiled its options down to two: stating in its documents that a “‘mega price increase’ and a
 9 potential Norvir liquid only [i.e., removing all other dosage forms from the market] are the two
 10 scenarios that we will need...to focus on building a communication platform for all.” The latter
 11 option would have pulled Norvir capsules from the market and left HIV patients only with a liquid
 12 form of Norvir that Abbott’s own executives admit “taste[s] like someone else’s vomit.” Other
 13 materials reveal that Abbott planned to make up a justification for this withdrawal – one based on
 14 its early discussions in 2002; executives considered misleading the public into believing that
 15 Abbott was diverting the capsules for humanitarian efforts in “the developing world (i.e. Africa).”

16 30. Other emails outlined two potential scenarios for the “mega price increase” in
 17 which Abbott radically increased the price of Norvir in an effort artificially to decrease demand
 18 for its competitors’ PIs. In both scenarios, they suggested leaving the price of Kaletra unchanged,
 19 thus giving Abbott a huge price advantage over PIs boosted by Norvir. They outlined a “rationale”
 20 for the proposed Norvir price increase, suggesting that Abbott mislead the public into believing
 21 that “it is no longer feasible for Abbott to provide a production line of Norvir capsules at the
 22 current price.” The emails, however, frankly admit the “weakness” of this “rationale” – its falsity.
 23 They expressed concerns of “exposure on price if forced to open books” and sought to “minimize
 24 any federal investigations regarding price increases in the US.”

25 31. An Abbott slide presentation created around the time of these emails further
 26 illustrates the illegitimate motives behind Abbott’s price hike. The presentation reveals, for
 27 example, that Abbott sought to “[p]osition Kaletra as a more economical option for boosted ARV
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1 [anti-retroviral] therapy” and noted the “[p]otential for increased market share of Kaletra.” Abbott
2 acknowledged the illegitimacy of its plan, and recognized that it would incur significant
3 reputational harm by following its plan. Documents express an understanding that Abbott could be
4 perceived as a “big, bad, greedy pharmaceutical company,” that its CEO’s image could be
5 “[t]arnish[ed]” in industry organizations, and that the plan “[f]uels perception regarding lack of
6 Abbott commitment to HIV.” Nonetheless, Abbott found it easier to mislead the public regarding
7 an unprecedented price increase than to try to explain a complete withdrawal of Norvir capsules
8 from the market.

9 32. Setting aside repercussions to its corporate reputation – and to the community
10 infected by HIV – Abbott raised the price it charged for Norvir by 400 percent just two weeks
11 after GSK began selling Lexiva. This price increase was unprecedented and totally unexpected
12 outside Abbott. Shortly after the “mega price increase,” a senior Abbott executive congratulated
13 Abbott’s virology sales team. He told them, “It’s too bad you’re giving a lump of coal to BMS and
14 GSK for the holidays but such is life.”

15 33. Outside of its disregard for its own reputation and for the welfare of the HIV/AIDS
16 community, Abbott was also willing to incur direct financial penalties in hiking the price of Norvir
17 by 400 percent in 2003. Pricing rules that dictated what the government will pay for drugs
18 imposed a penalty on companies that tried to raise prices more than the percentage increase of the
19 Consumer Price Index. Because of the 400 percent price hike – a radical price increase well above
20 that of the Consumer Price Index – Abbott wound up getting approximately 70 percent less
21 revenue on each sale of Norvir paid for by key government programs. This was an enormous
22 sacrifice of revenue as government purchases cover half of the purchases of HIV/AIDS drugs.

23 34. Because of the 400 percent price increase of Norvir, the cost of boosted PI
24 treatments sold by GSK and other Abbott competitors skyrocketed. Abbott’s price hike alone
25 escalated the wholesale acquisition cost of GSK’s boosted Lexiva treatment from \$19.43 to
26 \$33.15. The wholesale acquisition cost of Kaletra, Abbott’s PI treatment, however, remained
27 unchanged at \$18.76.

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1 35. Abbott’s “mega price increase” and the timing of that increase to follow closely
2 upon Lexiva’s release had a massive disruptive effect on GSK’s ability to promote its drug –
3 dooming it to a failed launch from which it could not recover or respond. HIV treaters and patients
4 were outraged by the price hike as Abbott expected. For example, the Organization of HIV
5 Healthcare Providers, which represents physicians collectively treating approximately 85,000
6 patients with HIV, wrote Abbott on January 20, 2004, admonishing that Abbott’s price hike was
7 “taking advantage of the monopolistic situation, where [its] product is the only effective protease
8 inhibitor boosting agent.” Many patients and doctors expressed their anger and concern directly to
9 GSK. Because Abbott had pursued a “recommended” strategy of delaying announcement of the
10 price hike until shortly after GSK released Lexiva, GSK representatives spent the better part of
11 Lexiva’s launch period responding to infuriated doctors and patients who complained to GSK
12 about the price increase and expressed reluctance to use the drug until issues surrounding Abbott’s
13 price increase could be resolved. GSK lost the opportunity to promote boosted Lexiva to which it
14 was entitled and that it believed it had secured through its license agreement with Abbott.

15 36. True to its pre-hike plan, Abbott concealed from the public the illegitimate goal of
16 increasing Norvir’s price. According to news articles published shortly after the price increase,
17 Abbott representatives publicly stated – in direct contradiction to the internal Abbott materials
18 cited above – that the company had not considered the effect of Norvir’s price increase on Kaletra
19 sales or raised the price for the purpose of driving patients to Kaletra. Abbott’s false and
20 misleading communications had the intention and effect of further confusing prescribers and
21 purchasers about the real impact of the price increase among different classes of PI patients, and
22 thus further harmed Lexiva’s uptake by the market in the months following its launch.

23 37. Abbott further attempted to manage the fallout from its Norvir price increase by
24 publishing misleading comparisons of PI prices. In promotional and informational materials about
25 Norvir after the price increase, Abbott represented that Norvir was the lowest-priced PI on the
26 market.

1 38. The Department of Health & Human Services (DHHS) responded with a Warning
2 Letter to Abbott about such materials, calling Abbott's price comparison chart "false or
3 misleading in violation of section 502(a) of the Federal Food, Drug, and Cosmetic Act (Act) (21
4 U.S.C. 352(a))." Specifically, DHHS stated that the price chart was misleading because it
5 compared a "subtherapeutic dose of Norvir (100 mg once daily) to the labeled dosing regimens of
6 other antiretroviral agents" and it "implies that Norvir may be used other than in combination
7 therapy, when it is not labeled for such use." Abbott did not contest the FDA letter, choosing
8 instead to send a letter to healthcare providers retracting and "clarifying" its false statements.

9 39. The price hike had the effect of using Abbott's monopoly power over PI boosters to
10 unnecessarily handicap its competitors in the boosted PI market, where Abbott was already the
11 market leader. For example, as a result of the price hike, Abbott was able to maintain Kaletra's
12 market share while GSK lost anticipated market share for Lexiva. At this point, GSK and others
13 had sunk substantial resources into promoting their PIs with Norvir under license agreements with
14 Abbott. It was not feasible to start over from scratch. For example, it had taken GSK over seven
15 years and hundreds of millions of dollars to bring Lexiva to the market. These high barriers to
16 entry meant that the market was locked into Norvir for PI boosting for the foreseeable future.

17 40. In addition, GSK could not respond to the price increase. GSK briefly considered
18 reducing the price of Lexiva to compensate for the Norvir price increase. It quickly realized it
19 could not do so without suffering an overall decline in revenues and profits even if it successfully
20 saved the sales that Abbott had targeted. Because of pricing rules to the government, GSK could
21 not reduce the price of Lexiva in the private sector where GSK felt the largest effect of the Norvir
22 price hike without losing significant revenues in the government sector of the market where
23 Abbott incurred a penalty for the Norvir price hike. For this reason, as well as the magnitude of
24 the price hike in relation to the price of Kaletra, it became prohibitively expensive for GSK to
25 respond to the price increase.

26 41. Abbott's decision to raise the price of Norvir by 400 percent was unprecedented
27 and taken in bad faith. The 400 percent price hike immediately after GSK's release of Lexiva
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1 dashed GSK's reasonable expectation that, by virtue of the license for which it had paid, it would
2 be able to promote the co-prescription and co-administration of its PI products with Norvir at
3 prices competitive with those of Kaletra and other PIs. Moreover, by announcing its price hike
4 right after GSK launched Lexiva, Abbott left GSK no realistic options to reestablish Lexiva's
5 value in the minds of the purchasing and prescribing public or otherwise to mitigate the effects of
6 Abbott's action. As Abbott's internal emails and documents illustrate, Abbott's bad faith conduct
7 was done knowingly and intentionally to interfere with sales of Lexiva and other boosted PIs.

8 42. As a direct and proximate result of Abbott's wrongful misconduct, GSK has lost
9 market share in the boosted PI market that it reasonably expected to achieve under the Abbott
10 license, has lost profits as a direct consequence of Abbott's misconduct, and has incurred other
11 damages. These losses were direct, foreseeable, and the invariable consequence of Abbott's
12 misconduct.

13 **HARM TO COMPETITION**

14 43. Abbott voluntarily entered into license agreements with its competitors, including
15 GSK, to promote boosted PIs for administration with Norvir.

16 44. Through its long-standing, voluntary course of dealing with its competitors, Abbott
17 has facilitated the market for boosted PIs using Norvir and caused its competitors to anticipate
18 incremental, rather than unprecedented and exorbitant, price increases for that drug.

19 45. Subsequent to establishing this course of dealing, Abbott radically changed course
20 and artificially and unreasonably raised the price of Norvir when co-prescribed with its
21 competitors' boosted PIs, like Lexiva, while keeping the price of Norvir low when used in
22 Abbott's own boosted PI, Kaletra. As a direct and proximate result, Abbott's misconduct has
23 artificially reduced the demand for the boosted PIs of GSK and Abbott's other competitors, while
24 artificially increasing demand for its own boosted PIs. Abbott's unlawful misconduct thus enabled
25 it to monopolize or have a dangerous probability of monopolizing that market.

26 46. Abbott's misconduct has directly and proximately harmed competition in the
27 market for boosted PIs. Abbott engaged in conduct that unnecessarily excluded and handicapped
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1 its competitors, including GSK, in order to acquire a monopoly in the market for boosted PIs.
2 Abbott harmed the competitive process without a legitimate business justification. Abbott elected
3 to make an important change in a voluntary pattern of conduct – after encouraging the promotion
4 of Norvir with its competitors’ PIs – that existed in a competitive market and had persisted for
5 several years. Abbott made a conscious choice to change this established pattern to the detriment
6 of its competitors by increasing the price of Norvir to unprecedented levels. Abbott’s justification
7 for its choice is pretextual and does not legitimately promote competition. Abbott’s conduct harms
8 competition on the merits, increases prices, limits the quality and availability of products, and
9 increases costs.

10 47. As a direct and proximate result of Abbott’s misconduct, Abbott’s competitors in
11 the boosted PI market, including GSK, have suffered declines in revenue and reductions in the
12 market share that they otherwise would have obtained. It was prohibitively expensive for GSK and
13 other Abbott competitors to respond to the price hike both because of the magnitude of the price
14 hike that Abbott took in relation to the overall price of Kaletra and because of government pricing
15 rules that would have required GSK and other Abbott competitors to lower the price of their PIs
16 on sales where the government was the payer (even though there was no competitive motive for
17 doing so because Abbott’s price hike on Norvir was ineffective in the government sector). GSK
18 and other Abbott competitors thus did not have an economically rational response to the price
19 increase even if they were equally efficient producers of PIs.

20 48. As a direct and proximate result of Abbott’s unlawful conduct, consumers – for
21 example, patients living with HIV/AIDS and the health care professionals who treat them – have
22 been deprived of the benefit of free and open competition in the boosted PI market and have been
23 injured in their business and property, for example, by:

24 a) paying more for boosted PI treatments than they would have in the absence of
25 Abbott’s unlawful conduct;

26 b) being denied the benefit of a broader variety of boosted PI treatments; and
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1 c) being denied the benefit of research and development that likely would have
2 resulted in alternative and superior forms of PI treatments.

3 **DAMAGES**

4 49. GSK's injuries are unique and are in addition to, not duplicative or derivative of,
5 any injuries suffered by its competitors or by consumers. There is a direct causal connection
6 between Abbott's misconduct and the harm to GSK. Abbott targeted markets in which GSK
7 participates, intended to harm GSK, and such harm was reasonably foreseeable.

8 50. As a direct and proximate result of, among other things, depriving GSK of the
9 opportunity to compete in fair and open markets and dashing GSK's reasonable expectations
10 under its license with Abbott, Abbott's breach of the covenant of good faith and fair dealing,
11 unfair business practices, and other unlawful conduct has had an adverse effect on the revenues
12 GSK should have received and will receive on sales of its boosted PIs. GSK has also lost
13 significant market share in the market for boosted PIs. GSK has further lost the benefit of the
14 bargain it struck with Abbott when GSK agreed to a license from Abbott. Abbott has taken for
15 itself part or all of the expected and reasonably anticipated benefit of the agreement it entered with
16 GSK. GSK's losses are direct, foreseeable and the invariable consequence of Abbott's
17 misconduct.

18 **TRADE AND COMMERCE**

19 51. Abbott's conduct has a direct, substantial, and reasonably foreseeable effect on
20 commerce within the United States and elsewhere, and competition in such commerce has been
21 and continues to be substantially reduced.

22 52. Abbott's conduct has a direct, substantial, and reasonably foreseeable effect on
23 commerce within the States of California, North Carolina and elsewhere, and competition in such
24 commerce has been and continues to be substantially reduced.

25 **CONTINUING WRONGDOING AND EQUITABLE TOLLING**

26 53. Abbott's wrongdoing alleged herein involved multiple, continuous unlawful acts
27 that occurred over many years and are continuing. GSK's discovery of the wrongful conduct by
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Abbott was delayed by Abbott's affirmative attempts to conceal evidence, including by misrepresenting the true purpose and effect of the Norvir price hike. As a result, all applicable statutes of limitations have been tolled.

COUNT 1 – BREACH OF COVENANT OF GOOD FAITH AND FAIR DEALING

54. GSK realleges and incorporates by reference paragraphs 1 through 53 as if set forth herein in full.

55. GSK and Abbott entered an agreement in which Abbott gave GSK a license to promote its boosted PIs to be administered with Norvir. GSK paid substantial sums of money for this right. GSK also reduced the value of royalties it expected to receive from Abbott pursuant to a contemporaneously negotiated agreement relating to a different set of products and technologies. Abbott knew, upon entering the agreement licensing promotion of Norvir with GSK's PIs, that the agreement's sole purpose was for GSK to exploit Norvir in combination with Lexiva and other PIs. The terms of the agreement, as negotiated, were based upon GSK's reasonable expectation that Norvir would continue to be commercially available for use as a PI boosting agent and that future increases in the price of Norvir would be consistent with past increases. Abbott's 400 percent price increase for Norvir severely injured GSK's rights, dashed its expectations under the license and thwarted GSK's ability to benefit from the contracted rights. The price increase was illegitimate, arbitrary, capricious and done in bad faith. The price increase devastated the value of the license agreement to GSK.

56. As a direct and proximate result of Abbott's intentional, wrongful conduct, GSK has been prevented from receiving its reasonably expected and justifiable fruits under the contract.

57. Abbott's bad faith conduct has directly and proximately caused actual damage or loss to GSK, including the loss of profits from sales of its PIs, including Lexiva. These losses were foreseeable, and a direct and invariable consequence of Abbott's misconduct.

COUNT 2 – VIOLATION OF STATE UNFAIR TRADE PRACTICE STATUTE

58. GSK realleges and incorporates by reference paragraphs 1 through 53 as if set forth herein in full.

59. This claim is brought to recover treble damages for Abbott's violation of the North Carolina Unfair Trade Practices Act, N.C. Gen. Stat. § 75-1.1.

60. The actions of Abbott constitute unfair and deceptive practices. Abbott's actions as alleged above (1) constitute inequitable assertions of Abbott's power or position, (2) violate the requirement that parties at all levels of commerce act in good faith and engage in fair dealings because Abbott has sought to destroy or injure the right of GSK to receive the benefits of the parties' arrangement, and (3) constitute deceptive acts.

61. More specifically, as alleged above, Abbott, among other things, manipulated and exploited its position of power over Norvir to lead its competitors to undertake a certain course of conduct and to expect incremental, not extraordinary, price increases and then, after receiving substantial sums of money from those competitors for a license, increased the price of Norvir by 400 percent so as to restrict the commercial availability of Norvir and Abbott PI treatments boosted with Norvir.

62. Further, in furtherance of, and as part of its plan to bolster Kaletra's sales and market share by quintupling the price of Norvir, Abbott deliberately deceived its competitors and the public as to the true and illegitimate nature of the price increase. As alleged above, Abbott further misrepresented the pricing of Norvir to the public, compounding the injury to commerce and to its competitors' position in the market, including GSK's position in the market.

63. As a proximate result of Abbott's violations of the North Carolina Unfair Trade Practices Act, GSK has been substantially injured in its business and property and is likely to be injured further in its business and property. Abbott has damaged GSK and taken for itself part or all of the expected and reasonably anticipated benefit of the agreement it entered with GSK. The amount of such injury will be determined at trial. Unless the defendant is enjoined from further violations of the North Carolina Unfair Trade Practices Act, GSK will continue to suffer injury from the illegal acts of the defendant.

PRAYER FOR RELIEF

WHEREFORE, GSK prays for relief as follows:

1 A. For damages resulting from Abbott's breach of the covenant of good faith and fair
2 dealing in an amount to be determined at trial;

3 B. For damages resulting from Abbott's violation of the North Carolina Unfair Trade
4 Practices Act in an amount to be determined at trial, and the trebling of such damages;

5 C. For an award of pre- and post-judgment interest on damages;

6 D. For an award of attorneys' fees and costs, and other expenses;

7 E. For such equitable and injunctive relief as is necessary to undo the effects of
8 Abbott's wrongful conduct and to prevent Abbott from repeating that conduct; and

9 F. For an award of such other and further relief as this Court deems just and proper.

10 Dated: March 10, 2015

HUESTON HENNIGAN LLP
THE LANIER LAW FIRM P.C.

11
12
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DEMAND FOR JURY TRIAL

GlaxoSmithKline hereby demands a trial by jury on all issues triable to a jury.

Dated: March 10, 2015

HUESTON HENNIGAN LLP
THE LANIER LAW FIRM P.C.

By: /s/ Brian Hennigan
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EXHIBIT A


THE WALL STREET JOURNAL.
 ONLINE

January 3, 2007

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Abbott Laboratories' Norvir Plan

January 3, 2007

In this Sept. 12, 2003, email, Jesus Leal, then an executive at Abbott Laboratories, addresses a colleague about pricing of an Abbott AIDS drug, Norvir. The drug is paired in treatment regimens with drugs made by Abbott's rivals. Abbott at the time was hoping to increase sales of Kaletra, its flagship AIDS drug. Mr. Leal offers two ways of increasing Norvir's price as a way of making the rival drug regimens more expensive and making patients turn to Kaletra. He concludes by recommending another approach: removing Norvir capsules from the U.S. market and forcing patients who need Norvir to drink a foul-tasting liquid form of the drug. Below that, see excerpts from an internal slide presentation about the company's plan to communicate the Norvir price change.

Italics indicate editors' notes.

From: Jesus Leal

Subject: Pricing/capsule withdrawal

Sent: 9/12/2003 9:03 a.m.

As promised, below are some more thoughts to help you with the messaging. Please don't be stunned by the outcome of the thought process because although it is a continuation of yesterday's conversation, the conclusion is quite different. What I have tried to do is to outline a straightforward strategy, the elements of the announcement without intertwining a convoluted story that won't hold up to scrutiny by the press or the public and identify glaring weaknesses.

Option 1: Price Increase A

Strategy: One price policy for Abbott protease inhibitors

Announce free/reduced cost Norvir liquid for patients on Norvir as of October 31st.

Announce price increase of Norvir capsules for all new patients to the price of daily Kaletra. Offer patients the choice to continue taking the capsules at the new price.

[Next, Mr. Leal outlines a public-relations defense of a price hike: Abbott originally planned to sell Norvir in a more-expensive 1200-milligram dose but ended up mostly selling the cheaper 100-milligram dose.]

Announce that Norvir dosing has decreased from 1200 mg/day to 100mg/day (for most new RXs), a 92% reduction in the daily volume required for patients.

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Rationale: The introductory dose of Norvir was 1200mg/day. Most new prescriptions for Norvir are currently written for 100mg. It is no longer feasible for Abbott to provide a production line of Norvir capsules at the current price.

Weakness: Exposure on price if forced to open books.

Option 2: Price Increase B *[This is similar to Mr. Leal's first option except it would give more consideration to existing patients by allowing them to continue to buy Norvir at the old, lower price.]*

Strategy: One price policy for Abbott protease inhibitors

Announce a stockpile of Norvir capsules at the old price to be held for all patients on Norvir capsules as of October 31st.

Increase the price of Norvir for all new patients to the price of daily Kaletra.

Rationale: The introductory dose of Norvir was 1200mg/day. Most new prescriptions for Norvir are currently written for 100mg. It is no longer feasible for Abbott to provide a production line of Norvir capsules at the current price.

Weakness: Exposure on price if forced to open books.

Option 3: Withdrawal of Norvir Capsules

Announce a stockpile of Norvir capsules at the old price to be held for all patients on Norvir capsules as of October 31st. Patients would register with a central specialty pharmacy and will be able to continue their Norvir without interruption.

Announce the withdrawal of Norvir capsules.

Announce a reformulation campaign for lopinavir/ritonavir combination. *[This refers to a new formulation of Kaletra that Abbott later introduced.]*

Announce the continued availability of Norvir solution. Announce a new lower price for Norvir solution (equal to the price increase of Kaletra)

Announce that Norvir dosing has decreased from 1200mg/day to 100mg/day (for most new RXs), a 92% reduction in the daily volume required for patients.

Rationale: The introductory dose of Norvir was 1200mg/day. Most new prescriptions for Norvir are currently written for 100mg. It is no longer feasible for Abbott to continue manufacturing Norvir capsules.

Weakness: The only weakness is an outcry that would be fueled by other major pharma companies that introduce new compounds that need boosting to be as effective as Kaletra. We should be able to expose their motivation.

...[Y]ou know that when I joined this discussion, I was in the camp of a price increase. As I wrote this email, I became convinced that Option 3 may be the best course for Abbott to follow. It will:

1. Provide capsules for all current patients
2. We can provide price protection for all patients currently on Norvir capsules
3. Minimize any federal investigations regarding price increases in the US
4. It will significantly level the competitive playing field regarding convenience

The third and fourth points are the convincing points for me. there is no way that we can continue to provide the products and services to the HIV community if we continue to trade a prescription of Kaletra for a prescription of Norvir at 100mg. If we were to allow this to continue to occur, both Abbott and the HIV community would suffer from our inability to provide the level of support that they have been accustomed to.

If BMS [*Bristol-Myers Squibb, maker of a rival AIDS drug taken with Norvir*] were serious about the community, immediately after this announcement, they should offer to purchase Norvir capsules from us at the price point needed for them to secure supply.

* * *

Excerpts from an internal Abbott Laboratories slide presentation titled "HIV Communications Plan," dated Sept. 24, 2003:

Considerations for Strategic Pathways

Re-pricing Norvir 4x-6x current price

Pro

- Position Kaletra as more economical option for boosted ARV [*anti-retroviral*] therapy
- Ensure access to all Abbott ARVs
- Potential for increased market share for Kaletra
- Patients not harmed, as nearly all are covered by private insurance (fixed co-pay), Medicaid and ADAP [*AIDS drug assistance programs*]
- May restrict formulary access to Norvir

Con

- Lack of perceived value for ritonavir [*Norvir*] relative to new price
- Damages goodwill efforts toward responsible pricing, ADAP support and Global Care Initiatives
- Backlash from advocacy community, legislators, physicians
- Fuels perception regarding lack of Abbott commitment to HIV
- Tarnish [*CEO*] Miles [*White's*] debut as PhRMA [*Pharmaceutical Research and Manufacturers of America*] chair and impact on global perception of pharmaceutical industry
- Position as big, bad, greedy pharmaceutical company
- U.S. price premium puts drug at higher risk for re-importation

Assumptions/Considerations

- ADAP freeze extends through June '04; consider extension as goodwill gesture
- Price increase is specific to U.S. market

Withdrawal Scenario #1

Phase-down withdrawal of SEC [*soft-elastic*] capsules in U.S., transition to liquid. Commitment of capsules to philanthropic efforts in Africa.

Pro

- Maintain only convenient boosted PI [*protease inhibitor*] regimen option in U.S. through liquid availability
- Indirectly removes pricing from public debate

Con

- Limits therapeutic options for patients
- Contradictory approach with capsules remaining on ex-U.S. market [*market outside the U.S.*]
- Balance of philanthropic donation will not offset U.S. volumes
- Production capacity of Norvir correlated to Kaletra
- Philanthropic donations in AIDS to developing nations have high media appeal
- Perception of providing inferior product to Africa, as Norvir not used as stand-alone PI-based regimen
- Heavy upfront burden to re-educate physicians/patients; sales force-educating vs detailing
- Burden for LDC [*least-developed countries*] access shifting from industry to governments; no expectation for significant donation, leading to question why?
- Perception regarding lack of Abbott commitment to HIV patients in U.S.

Withdrawal Scenario #2

Phase-out of TPM [*third-party*] manufacturing and SEC form of Abbott HIV drugs. Phase 1 – Removal of Norvir capsules; Phase 2 – Conversion of Kaletra to Meltrex [*an easier-to-use formulation of Kaletra that Abbott later introduced*]

Pro

- Maintain only convenient boosted PI-regimen
- Meltrex provides improved convenience option for patients
- Removes pricing from public debate
- Portability, storage, taste of liquid inconvenient
- Lower risk of re-importation

Con

- Limits therapeutic options for patients
- Kaletra-Meltrex good news for patients offset by Norvir capsule withdrawal
- Questions surrounding why Norvir is not being developed in Meltrex formulation
- Ability to execute globally may be denied by regulatory agencies; consistency in phasing out of SEC may not be global; Zemplar and atrasentan SEC to follow. [*referring to other capsules Abbott made or planned to make; FDA subsequently declined to approve atrasentan, a prostate-cancer drug*]
- Ex-U.S. regulatory agencies may invoke compulsory license
- Production of ritonavir is correlated to Kaletra
- Heavy upfront burden to re-educate physicians/patients; Exchanges sales force time from selling to education
- Reinforces perception that Abbott is not committed to HIV; Damage to corporate reputation
- Competitors use simplicity of dosing to show consumer that low-dose liquid is workable

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EXHIBIT B



January 3, 2007

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PAGE ONE

New Regimen Inside Abbott's Tactics To Protect AIDS Drug

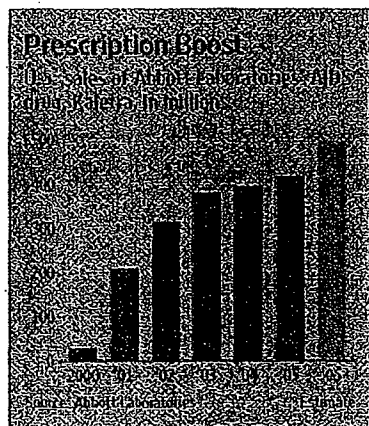
**Older Pill's Price Hike
Helps Sales of Flagship;
A Probe in Illinois**

By JOHN CARREY ROU
January 3, 2007; Page A1

In the fall of 2003, Abbott Laboratories grew worried about new competition to its flagship AIDS drug, Kaletra. Then it seized on an unusual weapon that helped Kaletra's global sales top \$1 billion a year, even as it exposed Abbott to criticism that it was endangering patients.

The weapon was an older Abbott AIDS drug called Norvir. It is a key part of drug regimens that include rival companies' pills. Previously undisclosed documents and emails¹ reviewed by The Wall Street Journal show how Abbott executives discussed ways to diminish the attraction of Norvir, with the goal of forcing patients to drop the rival drugs and turn to Kaletra.

At one point the executives debated removing Norvir pills from the U.S. market and selling the medicine only in a liquid formulation that one executive admitted tasted like vomit. The taste would discourage use of Norvir and competitors' drugs, the executives reasoned, and Abbott could claim it needed Norvir pills for a humanitarian effort in Africa. Another proposal was to stop selling Norvir altogether.



A third proposal carried the day: quintupling the price of Norvir. One internal document warned the move would make Abbott look like a "big, bad, greedy pharmaceutical company." But the executives expected a Norvir price hike would help Kaletra sales, and they bet any controversy would eventually die down.

They were right. Kaletra sales in the U.S. rose 10% over the next two years. Some objected that the price hike made it harder for patients who needed drug combinations pairing Norvir with non-Abbott pills to get their medicine. After an initial burst, the criticism faded, partly because Abbott exempted government health plans and AIDS drug-assistance programs from the Norvir price increase.

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The debate at Abbott over Norvir provides a rare inside look at a pharmaceutical company's efforts to maximize profits and thwart competitors. The industry has come under fire in recent years for tactics such as heavy marketing of drugs that offer little advantage over older products and paying generic-drug makers to delay the introduction of cheap copycats. Norvir represents a twist in which a company took advantage of its monopoly over one drug to protect sales of another, more profitable one.

An Abbott spokeswoman, Melissa Brotz, says the company never seriously considered pulling Norvir from the global market or withdrawing the pill version in the U.S. Abbott denies raising Norvir's price to protect Kaletra and says the increase didn't hurt its competitors since their drugs continued to gain market share and they later raised their own prices. It says the price increase was intended to better reflect Norvir's medical value after years of being underestimated.

Illinois Attorney General Lisa Madigan has been investigating Abbott's price hike for three years, saying it may be an example of unfair pricing that violates the state's consumer-fraud law. A lawsuit filed in U.S. district court in Oakland, Calif., by two AIDS patients and the Service Employees International Union Health and Welfare Fund alleges that Abbott broke antitrust law by using its market power to boost Kaletra sales. The case is scheduled to go to trial in early 2008.

New Class of Drugs

In the 1990s, a new class of drugs called protease inhibitors revolutionized the treatment of AIDS. By impeding the human immunodeficiency virus's ability to reproduce itself, these drugs turned the disease from a death sentence into a chronic, manageable illness for many patients.

Norvir, which received Food and Drug Administration approval in 1996, is a protease inhibitor. Serious side effects prevented it from being used as a stand-alone drug. But Abbott found that at small doses Norvir boosted the effectiveness of other protease inhibitors. Norvir soon received wide use in the drug combinations taken by AIDS patients.

In 2000, Abbott introduced Kaletra, which combined a new Abbott-made protease inhibitor with Norvir in a single pill. Kaletra's effectiveness and convenience quickly made it the most popular AIDS drug, with 35% of the protease-inhibitor market by 2003 and annual U.S. sales nearing \$400 million. By contrast, Norvir, when sold as a stand-alone drug, was bringing in less than \$50 million a year in the U.S.

ONLINE EXTRAS



• Reporter John Carreyrou speaks with Allen Thornell², a patient who is suing Abbott Laboratories over its move to sharply raise the price of

Norvir.

• Read the text of an email in which an Abbott vice president lays out options for boosting Kaletra sales³, and see excerpts from an internal slide presentation that expresses concern about Abbott being seen as "big, bad, greedy."

Then, in June 2003, Bristol-Myers Squibb Co. introduced a new protease inhibitor called Reyataz. Bristol-Myers presented a study it funded suggesting that Reyataz, boosted with Norvir, was as effective as Kaletra at holding HIV in check and had a better effect on cholesterol levels. Reyataz was also more convenient because it required fewer pills a day.

As Reyataz began gaining market share, Abbott executives considered ways to protect Kaletra sales. On Sept. 6, 2003, Jeffrey Devlin, Abbott's HIV marketing director, emailed a slide presentation to a colleague that

discussed two options: quintupling Norvir's price, or withdrawing Norvir pills from the U.S. market and leaving only the liquid version of the drug.

The pill withdrawal option would dramatically improve Kaletra's sales and cripple Reyataz, the presentation predicted, because the drug regimen that included Reyataz would suddenly become more expensive. It forecast that U.S. sales of Kaletra would grow by 20% to 30% between 2004 and 2006, while U.S. prescriptions of Reyataz would fall by 28% to 54% over the same period under the scenario. Anticipating that people would wonder why the Norvir pills were suddenly unavailable, the document recommended telling the American public that they needed to be sent "to the developing world (i.e. Africa)" as part of a humanitarian effort.

But Mr. Devlin fretted that forcing Americans to swallow Norvir in liquid form "will always be a tough sell." Abbott was keenly aware of the liquid's unpleasant taste. In a deposition the following year with investigators from the Illinois attorney general's office, John Leonard, Abbott's vice president of global pharmaceutical research and development, referred to liquid Norvir as "this fluid that has been — I'll just say it — characterized as tasting like someone else's vomit."

When Abbott briefly halted the production of Norvir pills in 1998 because of manufacturing problems, patients resorted to creative methods to block the liquid's foul taste. These included using a straw to shoot it to the back of their throats, coating their mouths with peanut butter or chocolate, and numbing their taste buds with ice or popsicles.

Backlash Foreseen

Foreseeing a backlash over the taste, Mr. Devlin recommended the price increase. But the liquid option stayed alive. On Sept. 12, 2003, Jesus Leal, then vice president of Abbott's virology franchise, recommended it in an email to a colleague. "Please don't be stunned by the outcome of the thought process," Mr. Leal wrote to her.

Mr. Leal's concern: A price hike on Norvir would be hard to justify. Abbott might claim it couldn't afford to produce the drug at the lower price, but it would face exposure "if forced to open books," he wrote. The liquid switch, on the other hand, would "minimize any federal investigations regarding price increases" he argued. Mr. Leal, who has since left the company, says today the email "was part of a long and vigorous debate within Abbott, and should not be taken out of context."

A slide presentation titled "HIV Communications Plan" and dated Sept. 24, 2003, reviewed the two options and added a third: pulling all formulations of Norvir from the global market. This radical step, the presentation said, would remove "pricing from public debate" and render moot any discussion of the liquid's taste. However, it noted that Abbott's "corporate reputation" would suffer.

PRICE CHECK

Key events surrounding Abbott Laboratories' increase in the price of AIDS drug Norvir:

- 1996: Abbott introduces Norvir.
- 2000: Abbott introduces AIDS drug Kaletra, which includes Norvir.
- June 2003: Bristol-Myers Squibb introduces Reyataz, a rival to Kaletra that is taken with Norvir.
- September 2003: In internal documents, Abbott executives discuss pulling Norvir from global market, quintupling the drug's price, or withdrawing Norvir pills from the U.S. market and leaving only its foul-tasting liquid form.

As for the price-increase scenario, the document listed as a "Pro" that health insurers might stop covering Norvir, which would hurt sales of other protease inhibitors and force patients to use Kaletra. Among the cons, it cautioned that the move would "tarnish" Abbott Chief Executive Officer Miles White's debut as chairman of the Pharmaceutical Research and Manufacturers of America, the industry's trade group, and "position" Abbott as a "big, bad, greedy pharmaceutical company." Abbott says this slide presentation was made by a public-relations firm working for the company at the time.

- October 2003: Company document warns Kaletra prescriptions will fall if Norvir's price isn't raised.
- December 2003: Abbott quintuples Norvir's price.
- February 2004: Illinois attorney general opens investigation into price increase.

In early October, as a second new protease inhibitor from GlaxoSmithKline PLC neared FDA approval, another internal document recommended the price increase. It warned that if Norvir's price wasn't raised, "the Abbott franchise will be severely threatened by the competitor's ability to 'piggy back' on Norvir's uniqueness." If Abbott took no action, it predicted, Kaletra prescriptions would fall 10% in 2004.

Abbott declined to make Messrs. Devlin, Leonard and White available for comment. Ms. Brotz, the Abbott spokeswoman, says Mr. White, who remains chief executive, didn't know that lower-ranking executives discussed forcing Americans to take Norvir as a liquid or ending its sale altogether. She says the executives were just brainstorming and quickly discarded some of the options. These executives weren't decision makers, she adds.

However, in a court brief filed in the California case last year opposing a plaintiffs' motion to unseal the documents, Abbott said they "were prepared by and for some of the most senior officers at the company as part of an enormously important strategic discussion about Norvir."

In December 2003, Abbott implemented its final decision: a 400% price increase. Norvir's U.S. wholesale price rose to \$257.10 from \$51.30 for 30 100-milligram capsules. The move made Kaletra a cheaper option for American AIDS patients. It raised the cost of using a Reyataz/Norvir regimen by \$2,504 to \$11,187 a year. In the case of regimens requiring more than once-daily Norvir boosting, the cost rose by \$5,000 or more a year. Kaletra at the time cost about \$7,000 a year.

Protest at Headquarters

As Abbott had foreseen, the price hike triggered an uproar. AIDS activists protested in front of the company's suburban Chicago headquarters and at its annual meeting of shareholders. Three hundred doctors banded together to boycott Abbott products and barred company sales representatives from entering their offices.

Abbott exempted Medicaid, Medicare and state AIDS drug-assistance programs from the price increase. It also announced that it would expand its own patient-assistance program. This enabled the company to argue that the increase was being shouldered by private health insurers, not patients.

Hollis Salzman, a partner with Labaton Sucharow & Rudoff, one of the law firms that brought the California case, says the Norvir price hike still made it harder for some patients to get drugs they needed. "Abbott single-handedly turned back the clock on the treatment of AIDS," she says.

Allen Thornell, an AIDS patient and plaintiff in the California case, says the 20% co-payment required by his insurance plan at the time jumped to \$1,000 a month from \$400 when Abbott raised Norvir's price. The new co-payment represented a third of his take-home salary. As a result, Mr. Thornell, 36, says he had to quit his job as head of Georgia Equality, a gay and lesbian organization. His current insurance has a low fixed co-payment. (Video interview⁴)

Ms. Brotz of Abbott says Mr. Thornell is not typical because most private health plans cap co-payments at a much lower level. She adds that people in his position are eligible for Abbott's

patient-assistance program. "Our intention was that no patient be denied access to Norvir," she says.

The Norvir price increase also affected institutions that weren't exempted, such as state prisons. The North Carolina Department of Corrections, which counts about 800 HIV-infected inmates, saw its Norvir costs rise to \$95,000 in the first quarter of 2004 from \$28,000 the previous quarter.

Abbott's move "created a huge price discrepancy" between Kaletra and rival drugs, says David Wohl, an associate professor at the University of North Carolina who works part-time treating infected inmates. Dr. Wohl resisted shifting patients to Kaletra unless he thought it was the best drug for them. He says resulting budget difficulties forced prisons to cut back on testing inmates for virus resistance.

In May 2004, the National Institutes of Health held a public hearing to consider a request by a consumer advocacy group that it authorize cheaper generic copies of Norvir to be made before the drug's patent expired. The NIH has legal authority to do that in cases where it has helped fund research into a drug, but it has never used this power.

John Erickson, a former Abbott scientist who did much of the research work on Norvir, spoke in favor of the request. He testified that it was unlikely Abbott would have funded Norvir's early development without a \$3.5 million grant it received from the NIH in 1988. Abbott doesn't dispute the grant was important but says it also invested its own money in HIV research, including \$300 million on clinical trials of Norvir. The NIH decided in Abbott's favor, saying it wasn't empowered to determine whether a drug's price was too high.

To justify the price increase, Abbott posted a cost-comparison chart on its Norvir Web site, showing that Norvir remained cheaper than other protease inhibitors. However, the chart implied that Norvir could be taken on its own at a 100-milligram dose when in fact it is approved at that dose only in combination with other protease inhibitors. The FDA ordered Abbott to remove the chart in June 2004, calling it "false and misleading," and Abbott complied.

Over time, the outcry faded. Private health insurers took a bigger blow but had little leverage, because they could hardly deny patients a lifesaving drug. Insurer Aetna Inc. sued Abbott but dropped the suit within days. Abbott also settled a suit brought by the AIDS Healthcare Foundation. The company agreed to support programs at the foundation, which provides free medicine to poor and uninsured AIDS patients. Financial terms weren't disclosed.

Dr. Wohl says Abbott has been "winning back some community goodwill, including from me" with new initiatives, such as a partnership with basketball Hall of Famer Magic Johnson to fight AIDS among African-Americans. Dr. Wohl says he has resumed making paid speaking appearances on behalf of the company.

U.S. sales of Reyataz, the Bristol-Myers drug, have grown despite Norvir's higher price. They reached \$370 million in the first nine months of last year, up 25% from the same period of 2005. Kaletra too has been selling well, thanks in part to a new formulation that improves convenience. U.S. sales of Kaletra grew 27% in the first three quarters of 2006 and are on track to reach \$500 million for the year.

Write to John Carreyrou at john.carreyrou@wsj.com⁵

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